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Feasibility and effects of an exercise-based intervention in prison inmates with psychiatric disorders: the PsychiActive project randomized controlled trial

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Abstract

Objective: To evaluate the feasibility and effects of a 12-week intervention combining aerobic and strength exercises in prison inmates with psychiatric disorders.

Design: Two parallel-group, randomized controlled trials.

Setting: A psychiatric prison hospital.

Subjects: Forty-one men prison inmates (mean age ± *SD* = 38.2 ± 9.2 years, mean prison duration ± *SD* = 2.6 ± 2.5 years) with psychiatric disorders (primarily personality disorder, *n* = 27; mean illness duration ± *SD* = 12.0 ± 10.5 years).

Interventions: Participants were randomly allocated to intervention group consisted of exercise plus usual care (*n* = 21) or control group which received usual care (*n* = 20) for 12 weeks. The exercise programme included three weekly sessions of group-based moderate-to-high intensity combined exercises designed and supervised by exercise professionals.

Main measures: Fitness and anthropometric measures were assessed using field-based tests (6-minute walk, Incremental Shuttle Walk, Arm-Curl, and Chair-Stand), handgrip dynamometry, bioelectrical impedance, and waist and hip circumferences.

Results: There were no adverse events, and 10 intervention participants withdrew. The remaining 11 participants attended a mean of 28 sessions, of which nine met the compliance criteria. Between-group change differences substantially favoured the compliance intervention group for the 6-minute walk (+21.2%), Incremental Shuttle Walk (+33.9%), Arm-Curl (+13.8%), waist (–3.5%), waist/height$^{0.5}$ (–1.7%) (–2.7%), waist/hip (–3.4%), and Body Shape Index (–3.3%) (–3.5%). Additional analysis showed beneficial effects of exercise participation on handgrip strength.

Conclusion: The intervention was safe, had a high dropout rate, and seemed to be effective for improving fitness and anthropometric measures in men prison inmates with psychiatric disorders who attended and participated in the exercise sessions.

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Introduction

Psychiatric disorders is a leading cause of cardiovascular disease[1] and premature all-cause death[2] worldwide. In 2010, the global economic burden of psychiatric disorder was comparable to that of cardiovascular diseases and higher than that of cancer, chronic respiratory diseases, and diabetes, and is expected to double by 2030.[3] Therefore, improving treatment for this clinical population is a global health priority.

A plethora of evidence[4,5] has consistently demonstrated that exercise-based interventions are a feasible, acceptable, and effective manner to improve both mental and physical health in this population. However, people with psychiatric disorders are 50% more likely than the general population not to meet physical activity guidelines.[6] Given that prison inmates also do not undertake regular physical activities,[7] it is possible that the combination of being a prison inmate and having a psychiatric disorder may exacerbate the tendency towards physical inactivity. There are very few peer-review studies on increasing exercise in the prison population,[8–10] and none investigating exclusively prisoners with psychiatric disorders. Understanding the feasibility and effects of exercise-based interventions on the health of prison inmates with psychiatric disorders is both a challenge and an opportunity for the public health and scientific community.

An essential aspect of understanding the effects of interventions on health is the use of adequate measures. Physical fitness[11,12] and anthropometric[13] measures have extensively shown to be strong independent predictors of all-cause and specific-cause morbidity and mortality. The aim of the current study was to evaluate the feasibility and effects of an exercise-based intervention programme on the fitness and anthropometric measures of prison inmates with psychiatric disorders. We hypothesized that the exercise programme would improve the aforementioned variables.

Material and methods

The study was part of the PsychiActive project and followed CONSORT (Consolidated Standards of Reporting Trials)[14] and CERT[15] (Consensus on Exercise Reporting Template) guidance. The protocol was registered at ClinicalTrials.gov (Identifier: NCT03352544) and was approved by the Hospitales Universitarios Vírgen Macarena and Virgen del Rocío Ethics Committee (1674-N-17) and the Spanish Ministry of Interior. All participants gave their informed written consent prior to enrolling in the study and after receiving information about the aims and protocol. There was no compensation for participation.

The study was conducted in a psychiatric prison hospital (Hospital Psiquiátrico Penitenciario de Sevilla, Spain). Subjects were recruited over a 4-week period by clinical staff members, comprising nurses, doctors, psychologists, and social workers. The medical chief selected those who met the requirements to participate. Subjects were included if they had a psychiatric disorder diagnosed by experienced psychiatrists, were aged between 18 and 65 years, and were stabilized on antipsychotic medication during the last month. Subjects with clinical instability, substance abuse, or any other condition contraindicating participation were excluded.

Baseline assessment was performed before the intervention (in April 2015) and included demographic, clinical, fitness, and anthropometric data measures. Follow-up assessment was performed after 12 weeks of intervention (in July 2015) and included fitness and anthropometric measures. Each assessment period lasted a week. After baseline measurements were taken, participants were allocated to the control (usual care) or intervention (exercise + usual care) group, according to a balanced block randomization process using SPSS (50%/50% of all the cases) conducted by a researcher (D.M.-I.) not involved in the assessment. The intervention started 1 week after randomization. Baseline and follow-up assessments, design, implementation, and supervision (face-to-face) of the intervention throughout the study period were conducted by two exercise physiologists (J.B.-A. and M.A.O.-C.), with more than 3 years of experience researching the subject of exercise in people with psychiatric disorders.

Measures

Feasibility was measured as follows:

- Recruitment rate: number of randomized participants divided by number of enrolled subjects.
- Attendance: number of exercise sessions the participant completed prescribed exercises.
- Persistence: number of weeks the participant attended at least one exercise session.
- Dropout: number of randomized participants who did not complete their treatment.
- Reasons for non-attendance and dropout.

Cardiorespiratory fitness was assessed with the distance walked (without running or jogging) in the 6-minute walk test (to the nearest 0.1 m) and in the Incremental Shuttle Walk Test (to the nearest 10 m) according to Rikli and Jones[16] and Singh et al.,[17] respectively. To ensure maximal effort and avoid ceiling effect in the Incremental Shuttle Walk Test, the modified version without limiting by levels of velocities was used.

Handgrip strength was assessed to the nearest 0.1 kg with a hand dynamometer (TKK 5401 Grip-D, Takei, Tokyo, Japan). Participants in erect stance and with the arm in complete extension were instructed to squeeze the handle as fast and as hard as possible for 5 seconds. The test was performed twice (alternately with both hands) with a 1-minute rest between trials, and the maximum value of the four attempts was used. To account for individual differences in body mass, we have used relative grip strength (i.e. handgrip strength/body mass, both in kg) for the analysis.[18]

Upper- and lower-body strength were measured using the 30-second Arm-Curl test and the 30-second Chair-Stand test, respectively, as explained elsewhere.[16] For the Arm-Curl test, the best score of the two attempts (one for each arm and with a 1-minute rest between trials) was used. Concerning the Chair-Stand test, only one attempt was performed.

For each fitness test, except for handgrip test, multimedia explanations are available on the following link: https://upotv.upo.es/series/58da216a238583e0478b48f0. For each test, the same instructor explained the protocol, gave a demonstration prior to start, supervised, verbally encouraged participants (using standardized encouragements for the 6-minute walk test[16]), and recorded the results.

Anthropometric measures were collected in the morning after an overnight fast. Height was measured to the nearest 0.1 cm with a stadiometer. Weight, fat mass, and fat-free mass were measured to the nearest 0.1 kg via bioelectrical impedance analysis (InBody-770, Biospace, Seoul, Korea). Waist circumference was assessed at the midpoint between the last rib and the iliac crest, and hip circumference at the level of the greater trochanter. Circumferences were measured twice to the nearest 0.1 cm using a measuring tape (Harpenden Anthropometric Tape; Holtain, Dyfed, UK), and mean values were used. Then, following anthropometric indices were calculated:

- Body mass index = weigh/height^2; weight in kg and height in m.
- Fat mass index = fat mass/height^2; fat mass in kg and height in m.
- Fat-free mass index = fat-free mass/height^2; fat-free mass in kg and height in m.
- Waist/height$^{0.5}$ = waist circumference/height$^{0.5}$; both in m and cm.
- Waist/hip = waist circumference/hip circumference; both in cm.
- A Body Shape Index = waist circumference/body mass index$^{2/3}$ × height$^{1/2}$; waist and height in m and body mass index in kg/m^2.

Age, diagnoses, illness and prison duration, and medication were obtained from the participants' medical records. Antipsychotic medication was converted into chlorpromazine equivalent dose.[19] The Global Severity Index of the Brief Symptom

Inventory–18[20] was used to assess psychopathological severity over the past week. Smoking was self-reported.

Intervention. The exercise programme lasted 12 weeks and included three weekly sessions (Monday, Wednesday, and Friday) of group-based aerobic and strength exercises, detailed in Supplemental Appendix 1, and accompanied by the participants' preferred choice of music. In each session, the two supervisors first explained the exercise to be performed during the tasks, continuously reinforced exercise techniques, giving positive feedback, and encouraging participants to do their best throughout the session, and commended participants for their efforts at the end. Exercise duration and intensity were monitored with the SenseWear Mini armband (BodyMedia Inc., Pittsburgh, PA, USA), which combines triaxial-accelerometry with measurements of heat production, to accurately estimate energy expenditure during aerobic, resistance, and combined exercise.[21] All attendants wore the device on their left arm triceps muscle while training.

Usual care consisted of psychotherapy, pharmacological treatments, and group therapy (cognitive, educational, and creative/recreational activities such as painting and reading) facilitated by psychologists and social workers.

Statistical analysis

Analyses were performed on intention-to-treat and per-protocol bases. Intention-to-treat analyses included all randomized participants who provided baseline and follow-up data for every outcome measure. Per-protocol analyses included participants who attended at least 70% of the exercise sessions and the entire control group.

Between-group comparisons of baseline demographic and clinical characteristics were performed using unpaired *t*-tests (Student's for intention-to-treat and Welch's for per-protocol), Mann–Whitney *U*-test, chi-square test, or Fisher exact test, according to the nature and distribution of variable. Between-group comparisons of the percent change in fitness and anthropometric measures were performed using unpaired *t*-tests (Student's or Welch's) and Mann–Whitney *U*-test. These tests were carried out using SPSS Statistics for Windows, version 22.0 (IBM Corp., Armonk, NY), and adjustments for multiple comparisons were made using the Bonferroni method by dividing the significance level of 0.050 by the number of comparisons. Data were also assessed for practical/clinical meaningfulness using an approach based on the magnitudes of change. Cohen's *d* statistic determined the effect size of the standardized differences, and Hopkins' scale[22] and a customized spreadsheet[23] were used to determine the magnitude of the effect size.

Results

A participant flow diagram is shown in Figure 1, and baseline demographics data are presented in Table 1. A mean of 10.5 $\pm$ 2.3 participants (range, 6-16) from the intervention group attended each session, and duration of attendance was detailed in Table 2. Mean attendance and persistence for the 11 participants who completed the exercise programme were 28 sessions (range, 8-35), and 11 weeks (range, 7-12), respectively. Reasons for missed sessions were temporary exit from prison (29%) (due to permission (50%), participation in external activities organized by local mental health associations (38%), and trial attendance (12%)), conflicting schedules with training courses/prison work (24%), mental ill health (18%), physical ill health (11%), unknown (11%), and unspecified (7%). No adverse events occurred during the study for either the intervention or control group.

Baseline and changes in fitness and anthropometric measures in the intention-to-treat and per-protocol analyses are shown in Supplemental Table S1 and Table 3, respectively. The control group exhibited worse baseline values for fitness and anthropometric measures compared to the intervention group. Between-group change differences substantially favoured the intervention group for cardiorespiratory fitness and several anthropometric in both analyses. In addition, the per-protocol analysis showed substantial benefits for the intervention group in upper-body strength.

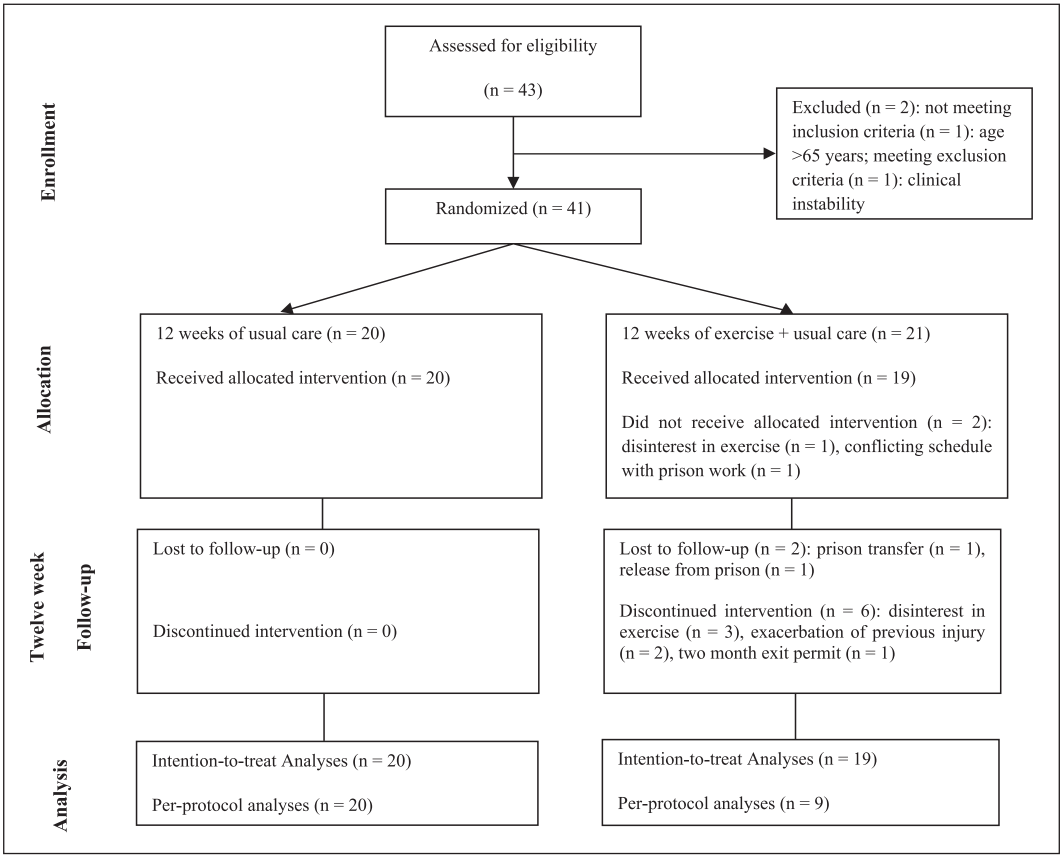

Figure 1. Participants flow diagram.

Additional analysis showed that the number of participants with low handgrip strength (<25th percentile of age- and gender-normative data from the National Health and Nutrition Examination Survey (NHANES) study[18]) increased in the control group (from 4 to 7) and decreased in the intervention group (from 2 to 0, both of the compliance group).

Discussion

Two major findings of the present study can be highlighted. First, slightly more than half of individuals allocated to the intervention participated in the exercise programme. Second, the exercise programme produced substantial benefits in cardiorespiratory fitness, upper-body strength, and several anthropometric measures in those people who attended and participated in the exercise group sessions. Furthermore, additional analysis suggested beneficial effects of exercise participation in handgrip strength.

Our rates of attendance (77%) and exercise dropout (48%) were similar to those reported in previous studies of combined exercise in prison, which ranged from 57% to 75%[8,10,24] and from 12% to 50%,[8–10,24] respectively. Interestingly, all of these studies were randomized controlled trials of group-based interventions in men. In addition, the studies that administered combined exercise as the sole intervention component in adults with psychiatric disorders of the general community reported lower dropout (ranging from 0% to 36%)[25–31] and similar attendance rates (ranging from 71% to 85%),[25,26,28]

Table 1. Characteristics of the participants.

	All (n = 41)	Control (n = 20)	Intervention (n = 21)	Compliance (n = 9)	Non-compliance (n = 12)
Age (years)	38.2 ± 9.2	39.3 ± 10.1	37.1 ± 8.3	32.7 ± 8.4	40.4 ± 6.7
Illness duration (years)	12.0 ± 10.5	11.7 ± 11.3	12.3 ± 9.8	6.8 ± 4.1	16.4 ± 10.9
Prison duration (years)	2.6 ± 2.5	1.9 ± 1.3	3.3 ± 3.2	2.9 ± 3.3	3.7 ± 3.3
Chlorpromazine equivalent dose (mg/day)	674.3 ± 551.4	789.7 ± 661.9	564.4 ± 407.4	569.3 ± 390.3	560.7 ± 437.0
Psychopathological severity (0–72)[a,b]	2.8 ± 2.9	3.4 ± 3.5	2.2 ± 2.1	2.1 ± 2.2	2.4 ± 2.1
Smoking (current smoker)	32 (78.0)	18 (90.0)	14 (66.7)	8 (88.9)	6 (50.0)
Diagnoses					
Schizophrenia, schizotypal and delusional disorders	2 (4.9)	2 (10.0)	0 (0.0)	0 (0.0)	0 (0.0)
Mood [affective] disorders	1 (2.4)	0 (0.0)	1 (4.8)	0 (0.0)	1 (8.3)
Disorders of adult personality and behaviour	27 (65.9)	13 (65.0)	14 (66.7)	6 (66.7)	8 (66.7)
Neurotic, stress-related, and somatoform disorders	5 (12.2)	2 (10.0)	3 (14.3)	1 (11.1)	2 (16.7)
Mental retardation	4 (9.8)	1 (5.0)	3 (14.3)	2 (22.2)	1 (8.3)
Disorders due to psychoactive substance use	2 (4.9)	2 (10.0)	0 (0.0)	0 (0.0)	0 (0.0)

Values are the mean ± standard deviation or n (%). Compliance included participants who attended at least 70% of the exercise sessions. Non-compliance included participants who dropped out (n = 10) and who attended less than 70% of the exercise sessions (n = 2).
[a]Missing data. Reasons: Incomplete questionnaire data for psychopathological severity (control n = 2; intervention n = 2, both of the non-compliance group).
[b]Psychopathological severity was assessed using the Brief Symptom Inventory–18, with higher scores indicating greater severity.

Table 2. Mean duration of attendance per session in minutes.

	Mean	*SD*	Range
Total session	49.6	12.9	24–66
Total exercise (>1.5 METs)	44.0	12.3	23–61
Light exercise (>1.5–3 METs)	13.2	6.6	2–30
Moderate-to-vigorous exercise (>3–9 METs)	30.8	10.0	19–50
Very vigorous exercise (>9 METs)	0.6	0.8	0–3

METs: metabolic equivalents.
Data are based on 342 valid SenseWear records. The three invalid SenseWear records were due to technical errors. Exercise duration and intensity (in METs) were derived using manufacturer-specific algorithms (SenseWear Professional software version 8.1; BodyMedia, Inc., Pittsburgh, PA, USA).

Table 3. Baseline and between-group comparisons of the change from baseline to follow-up in fitness and anthropometric measures using per-protocol analyses.

	n	Baseline	Change from baseline (%)	Between-group difference (%)	Statistics	
		M ± *SD*	*M* ± *SD*	*M* (90% CL)	ES (90% CL)[a]	*P*
6-minute walk test (m)[b]						
Control	18	577.8 ± 60.5	–3.3 ± 9.5	21.2 (13.3)	1.23 (0.77)***	0.015
Intervention	9	667.8 ± 73.5	17.9 ± 20.7			
Incremental Shuttle Walking Test (m)[b]						
Control	18	484.4 ± 156.7	3.4 ± 19.9	33.9 (24.3)	1.35 (0.65)****	0.005
Intervention	9	697.8 ± 201.1	37.3 ± 37.7			
Relative handgrip strength[b,c]						
Control	20	0.533 ± 0.089	5.2 ± 13.8	–2.1 (8.2)	–0.16 (0.64)	0.662
Intervention	9	0.596 ± 0.109	3.1 ± 10.7			
Arm-Curl test (repetitions)[b]						
Control	19	27.6 ± 6.4	2.2 ± 19.3	13.8 (11.9)	0.76 (0.65)**	0.060
Intervention	9	34.9 ± 5.9	16.0 ± 15.8			
Chair-Stand test (repetitions)[b]						
Control	18	24.0 ± 6.0	4.3 ± 21.6	5.5 (10.2)	0.32 (0.59)	0.367
Intervention	9	32.0 ± 4.0	9.8 ± 9.3			
Weight (kg)						
Control	20	89.6 ± 18.4	–0.3 ± 6.6	–1.4 (3.4)	–0.24 (0.60)	0.501
Intervention	9	81.7 ± 8.8	–1.6 ± 4.0			
Body mass index (kg/m^2)						
Control	20	30.3 ± 4.7	–0.4 ± 6.6	–1.1 (3.3)	–0.19 (0.60)	0.595
Intervention	9	27.5 ± 3.7	–1.5 ± 3.8			
Fat mass index (kg/m^2)						
Control	20	9.4 ± 3.8	4.8 ± 19.8	–4.9 (21.0)	–0.17 (0.75)	0.680
Intervention	9	6.3 ± 2.6	–0.1 ± 32.2			
Fat-free mass index (kg/m^2)						
Control	20	20.9 ± 2.0	–1.8 ± 4.5	0.2 (3.2)	0.05 (0.68)	0.905
Intervention	9	21.2 ± 2.0	–1.6 ± 4.5			
Waist (cm)[b]						
Control	20	103.9 ± 13.0	–0.7 ± 6.5	–3.5 (3.7)	–0.70 (0.63)**	0.099
Intervention	9	93.8 ± 8.5	–4.1 ± 4.8			
Waist/height$^{0.5}$[b]						
Control	20	0.79 ± 0.10	–0.7 ± 6.5	–2.7 (2.7)	–0.73 (0.63)**	0.095
Intervention	9	0.71 ± 0.07	–3.1 ± 4.1			
Waist/hip[b]						
Control	20	1.012 ± 0.063	–3.4 ± 4.4	–3.4 (2.6)	–0.85 (0.64)**	0.033
Intervention	9	0.961 ± 0.034	–6.8 ± 3.4			
A Body Shape Index[b]						
Control	20	0.082 ± 0.004	–0.43 ± 2.57	–3.5 (3.7)	–0.74 (0.74)**	0.039
Intervention	9	0.079 ± 0.003	–4.12 ± 4.80			

ES: effect size, CL: confidence limits.

Analyses included participants who attended at least 70% of the exercise sessions and control group participants who provided baseline and follow-up data for every outcome measure. Unpaired *t*–Welch's test was used for comparisons, except for Incremental Shuttle Walking Test and Waist. Mann–Whitney *U*-test was used in these cases.

Table 3. (Continued)

[a]Threshold values for Cohen's ES were trivial (0.0–0.19), small (0.20–0.59), moderate (0.60–1.19), large (1.20–1.99), and very large (⩾2.00). The numbers of asterisks (*) indicate the likelihood for the between-groups differences to be substantial, with 1 symbol referring to possible difference, 2 to likely, 3 to very likely, and 4 to almost certain differences.
[b]Missing data. All were missing data from the follow-up except for one case in which a participant refused to perform the 6-minute walk test and Incremental Shuttle Walking Test both at baseline and at follow-up. In all cases, participants refused to perform the test except one in which a participant was injured and cannot perform the 6-minute walk, Incremental Shuttle Walking, and Chair-Stand tests at follow-up.
[c]Handgrip strength/body mass, both in kg.
Significant when $P < 0.004$ (i.e. 0.05/13 comparisons = 0.004).

with the exception of one study that had lower attendance (37%)[30] and another[31] that had higher attendance (97%). Considering the absence of adverse events, our combined exercise-intervention in men inmates with psychiatric disorders was safe and as feasible as other studies previously implemented in prisons and among people with psychiatric disorders in the general community.

The feasibility results may have been influenced by several aspects associated with reduced dropouts in people with psychiatric disorders,[5,32,33] including (i) implementing a group-based intervention of (ii) moderate-to-high intensity exercise (iii) delivered by exercise professionals and (iv) supervised throughout the duration of intervention. Other factors, such as (i) the use of participant's preferred music[34] and (ii) the variation of training sessions (comprising training methods, exercise selection, exercise equipment, and settings where exercises were performed), could have increased participation. On the contrary, the combined exercise training may have negatively influenced because it is associated with a greater dropout rate compared to aerobic or strength training alone in people with psychiatric disorders.[32,33] However, all dropouts and missed training sessions were unrelated to the intervention. Despite this, the large dropout rate is worrying and represents a challenge for future exercise interventions in this context.

The improvement in fitness concurring with previous studies that compared combined exercise versus control in prison inmates[8–10] and in people with psychiatric disorders in the general population,[25–27] and may be partly due to some exercise programme characteristics. In particular, at least one weekly session included resistance circuit-based training using low-intensity exercises and lasted 24–60 minutes, which is an effective training method for the concurrent development of cardiorespiratory fitness and muscular strength in healthy adults.[35] Furthermore, the implementation of an intervention programme with three weekly sessions and supervision by qualified exercise personnel may have also contributed to maximizing the cardiorespiratory fitness, which is in agreement with a recent meta-analysis of people with psychiatric disorders.[36] Regarding muscular strength, the improvements may also be explained because a third of the sessions included resistance exercises of moderate intensity performed at maximal intended concentric velocity and moderate volume (~50% of the maximum number of possible repetitions), which results in higher enhancements in muscular strength than does moderate-slow resistance training performed at low intended concentric velocity[37] and high volume.[38]

Strengths and limitations

One study strength was that the intervention was designed, implemented, and supervised by exercise physiologists. In addition, the duration and intensity of exercise were objectively recorded, while measurement errors were minimized by using the latest available model and algorithms of the activity monitor, and the limited amount of very high-intensity exercise undertaken.[21]

The two major limitations were the loss of approximately half of participants from the intervention arm and the small sample of men, which reduce the power of the analyses and generalizability of the current findings. However, the rates of recruitment and completion of baseline and follow-up assessments were higher than 95%, and the prison where the intervention took place is exclusively for men.

The current study could help to raise health professionals' awareness of the importance of considering exercise as medicine in prison inmates with psychiatric disorders and may encourage the scientific community to research the feasibility and benefits of exercise programmes in prison environments. Implications derived from this study could be around how to engage this particular population in undertaking exercise. For this, there is extensive literature on how people with psychiatric disorders[39] can be encouraged to participate in exercise that should be taken into account.

Clinical messages

- Approximately half of the eligible individuals allocated to the exercise intervention failed to participate.
- In those prison inmates prepared to undertake exercise, the provision of exercise within a group provided improvements in cardiorespiratory fitness, muscular strength, and anthropometric measures.

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Author contributions

J.B.-A. and D.M.-I. designed the study and wrote the protocol. All authors were responsible for the acquisition of the data. J.B.-A. and D.M.-I. performed the statistical analyses, and J.B.A. wrote the manuscript. All authors provided critical review of the manuscript and approved the final version.

Declaration of conflicting interests

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Supplemental material

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